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REMARKS

In order to expedite prosecution of this application, claims 5, 15, 18 and 19 have been canceled and claims 1, 11, and 20 have been amended to more clearly distinguish applicants' invention over the prior art. Reconsideration and allowance of the application as amended are respectively requested.

The present invention concerns a novel method for occluding the vasculature of a patient. To this end, a plurality of embolic coils are provided having a proximal portion and a distal portion. The proximal portion is relatively smooth and the distal portion has a relatively textured surface. The plurality of embolic coils are introduced into the patient's vasculature, using an introducer that is coupled to the proximal portion. The textured surface provides improved platelet adhesion compared to a non-textured surface, to promote clotting.

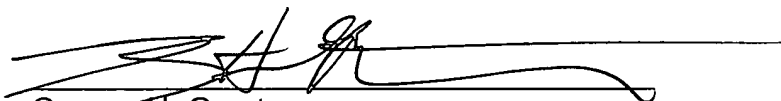
For the Examiner's convenience, an English translation of Plowiecki French Patent Application Publication 2,696,636 is enclosed. Plowiecki refers to a helically wound coil having its surface treated to obtain roughness. Likewise, Jacobsen et al. refers to an embolic device comprising a sequence of miniature beads having a surface that is preferably roughened or made porous. Nowhere do Plowiecki or Jacobsen et al. disclose, suggest or even hint that a proximal portion of the embolic device is relatively smooth, for use with an introducer that is coupled to the proximal portion. In fact, Plowiecki and Jacobsen et al. teach away from the use of a relatively smooth proximal portion by disclosing only a roughened surface. Applicants use of a relatively smooth proximal portion provides a controlled release when used with an introducer having a

detachment mechanism. This is a significant feature of applicants' system, which would not have been obvious to one having ordinary skilled in the art.

All of applicants' claims now very clearly bring out that the coils have a proximal portion and a distal portion with the proximal portion being relatively smooth and the distal portion having a relatively textured surface. As stated above, this is not taught by the prior art.

In view of the foregoing amendments and remarks, it is submitted that the present application is now in condition for allowance and an early Notice of Allowance is respectfully requested.

Respectfully submitted,
SEYFARTH SHAW LLP

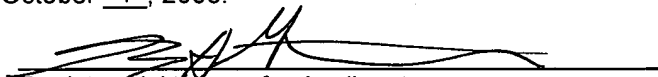


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Registered Attorney for Applicant
Date: October 7, 2003

19 REPUBLIC OF FRANCE
NATIONAL INSTITUTE
FOR INDUSTRIAL PROPERTY
PARIS

11 Publication no.: 2,696,636
(To be used for
reproduction orders only)

21 National registration no.: 92 12202

51 Int. Cl⁵: A 61 B 17/12

12 PATENT APPLICATION

A1

22 Filing date: October 13, 1992.

30 Priority:

43 Date application made publicly available:
April 15, 1994, Bulletin 94/15.

56 List of documents cited in the preliminary
search report: *See end of this booklet.*

60 References to other related national
documents:

71 Applicant(s): BALT, public corporation — FR.

72 Inventor(s): Plowiecki Léopold.

73 Holder(s):

74 Agent(s): Law Offices of Chambon.

54 Vascular occlusion system and usage method thereof.

57 The invention concerns a vascular occlusion system comprising at least one flexible tubular occlusion thread (3) which curls at rest and may be temporarily straightened in order to be inserted and pushed into a delivery catheter (5) until expelled from the latter through its distal end in order to reach the desired location of the vessel (2) to be treated, which is significantly remarkable in that the tubular thread (3) is open at least at one of its tips. In this fashion, the system may, among others, comprise a straightening guide wire (6) shaped as at least a semi-rigid wire with a diameter below that of the tubular occlusion thread (3) and designed to be inserted into the latter in order to straighten it for insertion into the catheter (5).

The invention also concerns a usage method for the system.

[see source for drawing]

FR 2,696,636 - A1

Vascular occlusion system and usage method thereof.

5 The invention concerns a vascular occlusion system and the usage method thereof.

 To suppress the blood supply to a tumor, or treat an aneurysm by limiting or suppressing blood pressure, an occlusion of the vessel in question or an occlusion of said aneurysm is used.

10 To obtain this occlusion, a solidifiable fluid or gel is known to be used.

 Placing an inflated cuff in the desired location is also known.

 Nevertheless, flexible and elastic threads, which wind up and/or curl have been used for many years.

15 These threads may even comprise whiskers in order to increase the desired clogging effects.

 A catheter is generally used for their delivery, a technique specifically mentioned in US 4,994,069.

 In this patent, occlusion threads are tubular but sealed at their tips.

20 To facilitate delivery, the inventor has devised a particularly effective set of means, hereinafter called occlusion system.

 This occlusion system comprises in a known manner at least one flexible tubular occlusion thread which curls at rest and may be temporarily straightened in order to be inserted and pushed into a delivery catheter until
25 expelled from the latter through its distal end in order to reach the desired location of the vessel to be treated, and is remarkable in that the tubular thread is open at least at one of its tips.

 Advantageously, the tubular occlusion thread itself consists of a helically wound tungsten filament having its surface treated to obtain
30 roughness, while heat-treated to provide for effortless cutting. The surface roughness facilitates clogging effects in a noticeable way.

 In comparison with prior art, the fact that the tubular occlusion thread is open allows for the provision of a straightening guide wire shaped as

at least a semi-rigid wire with a diameter below that of the tubular occlusion thread, designed to be inserted into the latter in order to straighten it for
5 insertion into the catheter.

Preferably, in this case, the system comprises at least a tubular pusher designed to be traversed by the straightening wire during the straightening operation in order to perform its pushing function thereafter.

10 To complete the occlusion of a vessel or aneurysm after the insertion of one or more occlusion threads, it is useful to have the ability to remove the last tubular thread after having assessed its necessary length, in order to cut it to the appropriate length.

Until now, a known technique has been to weld said thread to the tip of a pusher and then, in order to lodge this last thread definitively into place,
15 destroy said weld by a weak direct current.

This technique is particularly time-consuming.

For this reason, the inventor has devised a system which is remarkable in that it comprises at least a hook pusher fitted at its tip with a curved portion forming an elastic hook such as to allow it to grasp the tubular
20 occlusion thread and to move it within the catheter, while its curved tip straightens elastically, at least in part, as soon as said tip exits the distal end of the catheter, thus releasing the tubular occlusion thread when the hook pusher is pulled through the proximal end of the catheter.

Advantageously, in this case, the system comprises a tubular guide
25 designed to store the tubular occlusion thread and/or to facilitate its insertion with the hook pusher into the catheter through its proximal end.

The invention also concerns a method of using the aforementioned system.

30 The method according to the invention is remarkable in that it consists of:

- a) straightening a tubular occlusion thread by means of a straightening guide wire which traverses the tubular pusher,
- b) inserting the tubular occlusion thread thus straightened into the catheter by pushing it using the tubular pusher,

- 5 c) withdrawing the tubular pusher,
 d) pushing the tubular occlusion thread until ejected at the distal end
 of the catheter by means of a fluid injection and/or a long pusher.

One variation consists of repeating operations a) to d) at least once with other tubular occlusion threads and, in addition, of:

- 10 e) inserting, by means of the tubular guide and of the hook pusher, a
 tubular occlusion thread and partially expelling it in order to
 assess its necessary length,
 f) completely removing the tubular occlusion thread from the catheter
 at its proximal end, by removing the hook pusher,
 g) cutting the tubular occlusion thread to the desired length,
15 h) reinserting the tubular occlusion thread after adjusting the length.

The invention shall be understood more clearly and more particulars shall arise when reading the following description which refers to the annexed drawings wherein:

- 20 - figure 1 shows the delivery of several tubular occlusion threads to
 an aneurysm,
 - figures 2 to 6 show various stages of the method according to the
25 invention using the system according to the invention,
 - figure 7 shows the insertion of an occlusion thread by means of a
 tubular guide and a hook pusher,
30 - figures 8 to 10 show the expelling of the occlusion thread depicted
 in figure 7.

Figure 1 shows an aneurysm 1, on a blood vessel 2.

To treat the aneurysm 1, the technique consists of occupying the latter as fully as possible with a plurality of occlusion threads 3 (figures 2 to 10) which make up, by interweaving and convolution, an obstruction labeled 4 on figure 1, said threads being inserted by means of a catheter 5.

Each occlusion thread 3 according to the invention is a tubular thread 3 open at its tips and itself comprised of a helically wound filament as shown in the drawings.

The filament used is advantageously of a non-ferromagnetic material, and in particular of tungsten, heat-treated to provide for effortless cutting and surface treated for roughness.

Each occlusion thread is essentially a spring, which preserves or reassumes its helical shape elastically.

The usage method is illustrated in the drawings.

As shown in figure 2, a straightening guide wire 6 shaped as a wire with a diameter below that of tubular thread 3 is inserted into said thread 3, in order to straighten the latter.

The straightening guide wire 6 advantageously passes through a tubular pusher 7 (figure 2).

The tubular pusher 7 thus allows thread 3 to be pushed after its insertion into delivery catheter 5, as shown in figure 3.

As shown in figure 4, the straightening guide wire 6 is then removed (tubular pusher 7 may be maintained temporarily).

Thread 3 is then ejected from catheter 5 at its distal end, e.g., by injecting a contrast fluid using a syringe 8, as shown in figure 5, and/or by means of another pusher shown as 9 in figure 6.

When ejected, threads 3 become tangled by resuming their shape as shown particularly in figure 1.

To complete the filling of the aneurysm shown as 1 in figure 1, the last thread is used, shown as 3' in figures 7 to 10.

Thread 3' is inserted into catheter 5 using a tubular guide 10 (figure 7) and a hook pusher 11

(figures 7 to 10); tubular guide 10 may also serve as a means of storage for said thread 3'.

5 Hook pusher 11 comprises at its end, as its name indicates, a curved, elastic portion 12 which grasps the occlusion thread 3'.

It is thus possible to push thread 3' up to the distal end of the catheter (the end visible in figures 1 and 8 to 10).

10 Using fluoroscopy (given the opacity of the threads to X rays), the necessary length for this last element is assessed and, by means of the hook pusher 11, said thread 3' can be removed completely, cut to the appropriate length and reinserted.

15 In order to release thread 3' definitively inside the aneurysm, it is sufficient, as shown in figures 8 to 10, to expel said thread 3' at the distal end of the catheter such that the curved tip 12 of pusher 11 straightens elastically, as shown in figure 9.

By subsequently removing hook pusher 11, as shown in figure 10, the curved tip 12 straightens further before being returned to catheter 5 so as to release thread 3' completely.

20 Other means and variations can also be envisioned.

Thus, for instance, figures 8 to 10 show rings such as 13 and 13' on catheter 5, and 14, 14' on hook pusher 11.

Rings 13, 13' and 14, 14' are, e.g., of gold, such that the position of thread 3' in relation to the end of catheter 5 can be assessed by fluoroscopy.

25

30

CLAIMS

- 5 1) Vascular occlusion system comprising at least one flexible tubular occlusion thread (3, 3') which curls at rest and may be temporarily straightened in order to be inserted and pushed into a delivery catheter (5) until expelled from the latter through its distal end in order to reach the desired location of the vessel (2) to be treated, characterized in that the
10 tubular thread (3, 3') is open at least at one of its tips.
- 2) System according to claim 1, characterized in that the tubular occlusion thread (3, 3') itself consists of a helically wound tungsten filament having its surface treated to obtain roughness.
- 15 3) System according to any of claims 1 and 2, characterized in that the tubular occlusion thread (3, 3') is heat-treated to provide for effortless cutting.
- 4) System according to any of claims 1 and 2, characterized in that it comprises a straightening guide wire (6) shaped as at least a semi-rigid wire with a diameter below that of the tubular occlusion thread (3), designed to be
20 inserted into the latter in order to straighten it for insertion into the catheter (5).
- 5) System according to claim 4, characterized in that it comprises at least a tubular pusher (7) designed to be traversed by the straightening wire (6) during the straightening operation in order to perform its pushing function
25 thereafter.
- 6) System according to any of claims 1 to 5, characterized in that it comprises at least a hook pusher (11) fitted at its tip with a curved portion (12) forming an elastic hook such as to allow it to grasp the tubular occlusion thread (3') and to move it within the catheter, while its curved tip (12)
30 straightens elastically, at least in part, as soon as said tip (12) exits the distal end of the catheter, thus releasing the tubular occlusion thread (3') when the hook pusher (11) is pulled through the proximal end of the catheter.
- 7) System according to claim 6, characterized in that it comprises a tubular guide (10) designed to store the tubular occlusion thread (3') and/or
35 to facilitate its insertion with

the hook pusher (11) into the catheter (5) through its proximal end.

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[see source for figures 1-4]

[see source for figures 5-10]

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PRELIMINARY SEARCH REPORT

**NATIONAL INSTITUTE
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**established on the basis of the latest claims
submitted before commencement of search**

FR 9212202
FA 488862

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